CLIA UPDATE – April 2003 Division Of Laboratory Services Centers For Medicare & Medicaid Services

ENROLLMENT	Number of Labs	Number of POLs		
Laboratories Registered	179,638	100,813		
(Exempt/Non-Exempt/VA combined)				
Laboratories Registered (Non-Exempt Only)	173,712	99,370		
By Certificate Type				
Compliance (CMS Surveys)	21,027	13,873		
Waiver	98,193	47,226		
Provider Performed Microscopy	38,321	31,977		
Accreditation	16,171	6,294		

CLIA EXEMPT STATES	Number of Labs
New York (Except POLs)	2,841
Washington	2,741

CERTIFICATE OF ACCREDITATION BY ORGANIZATION (Non-Exempt only)	Number of Labs*		
Commission on Office Laboratory Accreditation	6,481		
College of American Pathologists	4,778		
Joint Commission on Accreditation of Health Care Organizations	4,022		
American Osteopathic Association	46		
American Association of Blood Banks	221		
American Society for Histocompatibility and Immunogenetics	128		

^{*}The above data represents labs whose membership with the accreditation organization has been confirmed. Some labs are accredited by more than one organization.

MOST FREQUENT DEFICIENCIES OVER TIME	ALL LABS			POLs				
Survey	1 st	2 nd	3 rd	4 th	1 st	2 nd	3 rd	4 th
Quality Control – Two levels per day of testing (D4006)	30%	13 %	7%	6%	35%	14%	8%	5%
Quality Assurance – No program (D7001)	27%	12%	7%	8%	29%	13%	7%	8%
Quality Control – Follow manufacturers instructions (D4001)	24%	15%	9%	9%	28%	16%	10%	10%

ENFORCEMENT

2001 Lab Registry contains 196 labs which had sanctions imposed in 2001.

Source: CMS CLIA Data Base